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12			
13	IN THE UNITED STATES DISTRICT COURT		
14	FOR THE SOUTHERN DIS	STRICT OF CAI	LIFORNIA
15	THE LARYNGEAL MASK COMPANY) Civil Action N	o. 07 CV 1988 DMS (NLS)
16	LTD. and LMA NORTH AMERICA, INC.,		RESPONSIVE CLAIM
17	Plaintiffs, v.) CONSTRUCT)	
18	AMBU A/S, AMBU INC., and AMBU	\	January 26, 2009 9:00 a.m.
19	LTD.,	Courtroom:	10, 2nd Floor
20	Defendants.) Honorable Da	na M. Sabraw
21		<i>)</i>)	
22	AMBU A/S, AMBU INC., and AMBU LTD.,))	
23	Counterclaimants,	<i>)</i>	
24 25	V.	,)	
25 26	THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC.,	,))	
27	Counter-Defendants.	<i>)</i>)	
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INTRODUCTION I.

Ambu agrees that in 1981 Dr. Brain "had a terrific idea" when he pioneered the field of laryngeal mask airway devices. (Ambu Br. 1.) Consistent with the ideals embodied in the Constitution, his pioneering invention served to "promote...the useful arts" (U.S. Const. art I, § 8, cl. 8) by spawning a broad range of innovations by him and competitors alike in this new field. Some of the innovations were directed to preventing cuff foldover. Dr. Brain and others worked for years to address this problem. The patent in suit is one result of Dr. Brain's ongoing effort to improve laryngeal mask airway devices.

Dr. Brain's '100 patent builds upon prior knowledge, but, like all improvement patents, is still entitled to the full scope of its issued claims. However, in numerous instances Ambu improperly urges this Court to import limitations to narrow the '100 patent's claims. For example, Ambu argues that the backplate must include a distal extension having a particular shape, and a "tube joint." Yet the claims require only that the backplate "define[] a passage" and nowhere mention a "tube joint" or a "backplate extension."

While the prior art may rely on an extended backplate to protect against foldover, the claimed invention of the '100 patent requires that the cuff, not the backplate, have a thicker and stiffer portion to protect against foldover. The '100 patent explains that the reinforcement can be part of the cuff, as claimed, or alternatively be part of the backplate. Nothing in the '100 patent or the Patent Office proceedings suggests that the goals of the '100 patent would be thwarted if the cuff were reinforced by something other than a continuous extension of the backplate. Rather, during Patent Office proceedings, claims specifically

Ambu suggests that somehow Dr. Brain's 1999 application directed to his improved design would impermissibly extend the patent monopoly. Yet, as evidenced by the references Ambu cites, at least one competitor filed patent applications in 1996 and 1998 on other designs to prevent foldover. Certainly Dr. Brain could not be expected to refrain from innovating and patenting improvements while competitors continued to do so. Nonetheless, improvement inventions by the pioneer and others are the desired result, not impermissible monopoly See În re Alappat, 33 F.3d 1526, 1553 n.12 (Fed. Cir. 1994) (Archer, C.J., concurring in part, dissenting in part) (emphasizing that others may "[see] further . . . by standing on the shoulders of giants" and learning from existing patents to create new inventions).

requiring that the reinforcement be part of the backplate were cancelled and replaced with the current claims that specify only that the "wall of the cuff" is "thicker and stiffer." These issued claims make no mention of the cuff reinforcement being a backplate extension or somehow being joined to the backplate.

Nonetheless, Ambu insists on re-writing the claims to exclude any cuff reinforcement other than a backplate extension. To reach that result, Ambu ignores portions of the intrinsic evidence that contradict its restricted view of the claim scope, focuses instead on one preferred embodiment, and resorts to unreliable extrinsic evidence, such as a conclusory expert declaration. Ambu also prematurely interjects its potential invalidity defenses into the claim construction analysis, ignoring both the presumption of patent validity and that the validity analysis lacks relevance at this stage of the proceedings. In contrast, the intrinsic evidence fully supports LMA's straightforward construction.

II. AMBU'S CLAIM CONSTRUCTION METHODOLOGY VIOLATES WELL SETTLED FEDERAL CIRCUIT PRECEDENT

A. <u>Claim construction starts with analysis of the intrinsic evidence, not with validity or infringement arguments</u>

Ambu's argument that the '100 patent claims must be limited to a backplate extension in order to be valid over the prior art is fundamentally misguided. (See, e.g., Ambu Br. 6 ("The '100 patent is distinguishable from the prior art only because of the slight modification made to how the backplate extension reinforces the cuff.")) The Federal Circuit has expressly rejected such a prior art-based approach to claim construction:

[V]alidity construction should be used as a last resort, not a first principle: 'we have limited the maxim [that claims are to be construed to preserve validity] to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.' Construction of the claims here is not so difficult a problem as to require resort to the validity maxim.

MBO Labs., Inc., v. Becton, Dickinson & Co., 474 F.3d 1323, 1332 (Fed. Cir. 2007) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc)). Ambu presents no grounds for treating this as the exceptional case in which validity issues should be factored into construing otherwise unambiguous claim terms. To the contrary, Ambu's expert

witness² did not identify any of the claims as indefinite in his own claim chart (Lampotang Open. Decl., Ex. D), and testified that he was "able to understand each of the claim terms that . . . are in dispute." Lampotang Dep. 99:7-10, Jan. 6, 2009 (Supp. Stowell Decl.³ Ex. P). Ambu's attempt to infuse the claim construction process with its invalidity defense is unjustified.

Even if a validity analysis were relevant, which it is not, Ambu's methodology of distilling the '100 invention to a single allegedly key element – the backplate extension – has been rejected by the Federal Circuit. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986) ("The court must view the claimed invention as a whole. . . We add, as a cautionary note, that the district court appeared to distill the invention down to a 'gist' or 'core,' a superficial mode of analysis that disregards elements of the whole.").

Ambu also argues that the '100 patent's claims must be limited to a particular type of backplate extension because the prior art generally shows extending the backplate to prevent foldover. This is a *non sequitur* for numerous reasons. *First*, Ambu employs improper methodology when it attempts to divine the claim construction by first speculating as to the scope of valid patent protection. *Second*, the claims are literally not directed to a backplate extension, but instead to a cuff thickening.

Third, in the Patent Office proceedings the pending claims were at one time directed to an extended backplate, but were later changed. In October 2005, the claims expressly called for a "backplate having a longitudinal distal rib . . ." (Woo Decl. Ex. R.) Those claims were rejected by the Patent Office. (Woo Decl. Ex. I.) The "backplate" claims were then cancelled and replaced in 2006 with the current claims to a thickened cuff. (Woo Decl.

² LMA does not concede that Dr. Lampotang, who has a Ph.D. in engineering, not an MD, and who lacks experience designing or using LMA devices, is qualified as an expert in the relevant field.

³ "Supp. Stowell Decl." refers to the Supplemental Declaration of Joshua Stowell in Support of Plaintiffs' Responsive Claim Construction Brief filed currently herewith.

Ex. M.) The cuff claims were allowed to issue. (Woo Decl. Ex. O.) Thus, the record shows that a backplate extension was not the basis for distinguishing the '100 patent from the prior art, but rather that claims not relying upon the backplate to reinforce the cuff reinforcement were deliberately sought and allowed to issue. This history counsels away from limiting the claims to require a backplate extension.

Fourth, Ambu's comparison of the claims to the prior art is incomplete and inconclusive. Dr. Lampotang opines that the claims as construed by LMA would be "obvious" and indistinguishable from the prior art. (Lampotang Open. Decl. ¶ 31; Lampotang Resp. Decl. ¶ 15.) Ambu relies on this opinion to conclude that LMA's claim construction is inappropriate. (Ambu Br. 7:12-14.) Yet Ambu contends the invention is not "sufficiently novel or non-obvious to qualify for patent protection" even when applying Ambu's own claim construction. (Ambu Br. 7:15-16.) Likewise, Dr. Lampotang admits that he never considered whether the claims as construed by Ambu would distinguish the prior art any better than under LMA's construction. Lampotang Dep. 204:21-205:22 (Supp. Stowell Decl. Ex. P). As a result, Ambu's detour into validity issues does not lead to a claim construction which it concedes will preserve patent validity, thus undercutting the purported logic of its analysis.

B. The claim language, not the descriptions in the specification, defines the scope of the patent

Ambu's argument that the '100 patent claims require, for example, a "tube joint," or "backplate extension," ignores basic claim construction precepts against importing limitations into the claim language from the specification.

As always, we begin our claim construction analysis with the language of the claim. There is a "heavy presumption" that the terms used in claims "mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1201 (Fed.Cir. 2002). After identifying the ordinary meaning of a disputed claim term, we turn to the patent's written description and drawings to determine whether that meaning is inconsistent with the patentee's use of the term, *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir. 2001), for example whether the patentee has specially defined the term or otherwise limited the scope of the claim. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1344 (Fed.Cir. 2001).

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27 28 However, the written description is not a substitute for, nor can it be used to rewrite. the chosen claim language. Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment. *Electro Med. Sys., S.A. v. Cooper* Life Scis., Inc., 34 F.3d 1048 (Fed. Cir. 1994).

Resonate, Inc. v. Alteon Websystems, Inc., 338 F.3d 1360, 1364-65 (Fed. Cir. 2003).

Sitting en banc in Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005), the Federal Circuit specifically cautioned against limiting claim language based on embodiments described in the patent specification:

[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. See, e.g., Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005) (claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification"). In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments. (other citations omitted).

Id.; see Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001) ("In short, it is the claims that measure the invention, as informed by the specification. Specifications teach, claims claim.").

Ambu contends that the limitations it seeks to add to the claim construction relate to features that will improve the operation of the device. Assuming this were true, Ambu's argument is still irrelevant because not every claim must meet every object of the invention or meet every identified need. Ventana Medical Sys., Inc. v. Biogenix Labs., Inc., 473 F.3d 1173, 1181 (Fed. Cir. 2006) ("When the claim addresses only some of the features disclosed in the specification, it is improper to limit the claim to other, unclaimed features."); Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("[P]atentees [are] not required to include within each of their claims all of [the] advantages or features described as significant or important in the written description.").

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The '100 patent discloses numerous embodiments and does not restrict C. the invention to having an extended backplate

Ambu ignores the broad claim language and attempts to limit the claim scope to a single preferred embodiment. The '100 patent discloses several different embodiments relating to the reinforcement for preventing cuff foldover. Ambu lacks justification for its narrow interpretation that would exclude the most relevant embodiment.

The first of the two disclosed embodiments for reinforcing the cuff has an extended backplate that pierces the center of the cuff wall, which is of uniform thickness. '100 patent col. 6 ll.7-10, 26-33, Figs. 5 and 8 (Stowell Decl. Ex. C). The "second embodiment" directly reinforces the posterior surface of the cuff, and is described beginning at the bottom of Column 7. *Id.* at col.7 1.62, Fig. 10. This second embodiment can be implemented in either of two ways: a) where "the distal rib of the backplate is applied to the posterior surface" of the cuff, id. at col.7 1.65—col.8 1.1; or b) it "may be" implemented by "a thickening of the posterior wall of the distal region of the inflatable main-cuff...," id. at col.8 11.9-11.

The claims to a "thicker and stiffer" cuff wall do not encompass the first embodiment, in which the reinforcement is suspended between the cuff walls rather than integrated into the cuff walls. Ambu admits this. (Ambu Br. 20-21.) Yet Ambu contends not only that the claims cover embodiment "2(a)," which also uses an extended backplate as the reinforcement, but further contends that is all that the claims cover. By insisting that the claimed reinforcement be part of the backplate, Ambu excludes entirely the thicker cuff wall embodiment "2(b)." What Ambu's construction would include - reinforcement by an extended backplate – is the wrong embodiment as the claims literally call for a thicker cuff, not a longer backplate. In contrast, LMA's construction would cover only embodiment "2(b)," and any variations of it.

Ambu's argument that "the only approach taught by the '100 patent...is extending the backplate" (Ambu Br. 7) is unsupported.⁴ Not only is it factually inaccurate in that it ignores

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⁴ This argument is also misplaced and premature because it attempts to collaterally attack LMA's proposed claim construction on validity grounds, this time arguing that the claim construction is not supported by the specification as required by 35 U.S.C. § 112. However, the issued claim is presumed valid and Ambu bears the burden of proving invalidity by clear

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the thickened cuff disclosure, it ignores the fact that the '100 patent never identifies the backplate extension embodiment as the one and only "invention." In the Summary of the Invention, the patent states that the "present invention" avoids foldover by:

incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading end of the LMA-device....In accordance with the invention, there is provided a laryngeal mask airway device...including a reinforcing rib incorporated into the distal end of the inflatable cuff. *In a preferred aspect*, the mask structure or backplate...has its back extended to the distal end of the cuff, in order to form the reinforcing rib.

'100 patent col.1 ll.48-67 (emphasis added).

Since the '100 patent specification does not even once, let alone repeatedly, describe the "present invention" or "invention as a whole" as having an extended backplate, the claims should not be so limited. Cf. Netcraft Corp. v. eBay, Inc., F.3d , 2008 WL 5137114, at *4 (Fed. Cir. Dec. 9, 2008) (limiting claim language based on the "specification's repeated description of the 'present invention'" as so limited, notwithstanding Court's acknowledgment that "use of the phrase 'the present invention' does not automatically limit the meaning of claim terms in all circumstances). Nor is the '100 patent specification analogous to the specification in Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340 (Fed. Cir. 2004). The '100 patent does not "consistently" rely upon the backplate structure to reinforce the cuff; it also describes thickening a portion of the cuff. *Id.* at 1347-48. The '100 patent specification is also unlike the one at issue in Alloc, Inc. v. ITC, 342 F.3d 1361 (Fed. Cir. 2003), which taught "that the invention as a whole, not merely a preferred embodiment, provides for [the limitation at issue]." Id. at 1369. The '100 patent makes express the distinction between the broader invention as a whole and a preferred aspect of extending the backplate.

and convincing evidence at the appropriate time. Ambu has not shown by the requisite clear and convincing evidence that one of skill in the art could not read the '100 patent as disclosing the claimed invention, an intensely factual question. See Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (satisfaction of written description requirement a question of "fact intensive nature"). Validity, like infringement, is assessed after claim construction, not before. TI Group Auto. Sys. v. VDO North America, L.L.C., 375 F.3d 1126, 1139 (Fed. Cir. 2004).

The false logic behind Ambu's attempt to restrict the claims to one preferred embodiment is illustrated by the arbitrary lines it draws to include helpful limitations, yet exclude from the claims numerous other optional features shown in the patent specification. On the one hand, Ambu includes an extended backplate. On the other hand, Ambu excludes a finger indentation and aperture bars. Yet all of the drawings and the description of a preferred embodiment set forth a finger indentation 140 on the airway tube. And, the description and all the drawings show mask aperture bars 115, 117. Ambu offers no basis for including an extended backplate and excluding a finger indentation and aperture bars. In truth, none of those features should be imported to limit the scope of the '100 patent's literal claims

Equally baseless is Ambu's attempt to limit the backplate to having both a tube joint and an extension to stiffen the cuff. That is not what the claims say or the specification requires. The claims expressly recite "a backplate defining a passage," and "cuff" that has a "thicker and stiffer" portion. Ambu greatly restricts that literal language to arrive at its construction.

D. Extrinsic evidence occupies a secondary and limited role in claim construction and expert witness claim construction opinions may be ignored

To support its proposed claim constructions and escape the literal breadth of the '100 patent's claims and the clear intrinsic evidence, Ambu relies upon several forms of extrinsic evidence, including the declaration of Dr. Samsun Lampotang. The *Phillips* Court outlined the limited purposes for which extrinsic evidence, such as expert testimony, learned treatises, and dictionaries, may be useful:

to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field

and cautioned that:

[W]e have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons. First, extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose

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of explaining the patent's scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence. The effect of that bias can be exacerbated if the expert is not one of skill in the relevant art or if the expert's opinion is offered in a form that is not subject to cross-examination. Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff. Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the "indisputable public records consisting of the claims, the specification and the prosecution history," thereby undermining the public notice function of patents.

Phillips, 415 F.3d at 1318.

Echoing the third reason above concerning the potential for unreliable expert testimony, the *Phillips* Court directed that "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court and a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* Indeed, expert testimony pertaining to claim construction, is entitled to no deference. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995) (en banc) (stating "the court has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it"), *aff'd*, 517 U.S. 370 (1996).

III. PROPER CONSTRUCTION OF THE DISPUTED CLAIM TERMS

The disputed claim terms are properly given their ordinary meanings consistent with the intrinsic evidence. Few terms are terms of art and no terms require a resort to extrinsic evidence.

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Α. **Independent Claim 1**

1. "Backplate"

LMA's Proposed Construction	Ambu's Proposed Construction
The body surrounded by and more rigid than the cuff	The relatively rigid mask structure of a laryngeal mask airway device, separate from the airway tube to which it is attached at a tube joint and on which a separate inflatable cuff is made fast as by gluing or welding together the two separate items ⁵

a. **Intrinsic Evidence**

Ambu argues that the backplate must include a "tube joint." However, a tube joint is not mentioned in the claim language, in the specification's description of the "present invention," or even each time that the specification describes the embodiment that Ambu touts. The '100 patent's Summary of the Invention can be broken down into four parts: first, two paragraphs describing the "present invention," '100 patent col.1 ll.48-63 (a reinforcing rib in the distal end of the cuff), followed by three "preferred aspects" thereof:

- 1. The reinforcing rib is formed by a backplate extension, id. at col.1 1.64 col.2 1.23;
- 2. A finger identation is added on the airway tube or backplate to assist in guiding the device during insertion, id. at col.2 ll.24-51; and
- 3. An elongated aperture and extended mask aperture bars to reduce the chance of epiglottis downfolding, id. at col.2 1.52 – col.3 1.13, including especially col.3 11.5-13.

The backplate is not described as having a tube joint in either of the two "present invention" paragraphs at the beginning of the Summary of the Invention section or in either

⁵ LMA explained in its Opening Brief that the term backplate should not be limited to require that the backplate and cuff be "made fast as by gluing or welding together the two separate Ambu's Opening Brief failed to address this proposed limitation of the backplate term, but it did address the same proposed limitation for the construction of the phrase "the cuff attached to the backplate." Accordingly, LMA will address this issue below in connection with that phrase.

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the backplate extension or extended mask aperture bar embodiments. Instead, in the entirety of the Summary of the Invention, a tube joint to connect the backplate to the airway tube is mentioned only in the second preferred embodiment concerning a finger indentation, presumably because it has relevance only to that preferred embodiment (for providing a thick enough wall to accommodate an indentation) (see LMA Br. 10-11). Given that the claims are directed to the broad description of the present invention, and not at the finger indentation preferred embodiment, a tube joint is not necessary to the claimed invention. There is no basis for concluding that the patentee intended to limit the claims only to a backplate having a tube joint. See, e.g., MBO Labs., 474 F.3d at 1334 ("limiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown" (citing *Phillips*, 451 F.3d at 1323)).

Thus, the absence of any reference to a tube joint in the present invention language or the necessity of a tube joint to the claimed invention renders inconsequential that the specification often describes a backplate as including a tube joint. See Phillips, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"). Indeed, the '100 patent specification also describes the backplate as having mask aperture bars and every figure shows a backplate having mask aperture bars. Just as the claim term backplate should not be interpreted as requiring mask aperture bars, nor should it be interpreted as requiring a tube joint. See MBO Labs., 474 F.3d at 1333 (reversing lower court's construction that the phrase "mounted on said body" required that the mounting be on the body's exterior) ("[t]he patent figures all depict the flange connected mainly to the outside, but patent coverage is not necessarily limited to inventions that look like the ones in the figures. To hold otherwise would be to import limitations from the specification, which is fraught with 'danger'.")⁶

Just as the claim term "backplate" should not be limited to having a "tube joint," Ambu's other proposed constructions that incorporate the requirement of a "tube joint" as part of the backplate (i.e., Ambu's proposed constructions for "distal rib," "proximal portion of the passage," and "passage axis") are similarly improper.

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Ambu also argues that the backplate is not "surrounded by the cuff" because the "tube joint extends above and beyond [the] cuff." (Ambu Br. 13.) Yet, the '100 patent specification itself states that the cuff "surrounds the hollow interior of the mask." '100 patent col. 1 1.60 (emphasis added). Ambu reproduces a figure from the patent in its brief and argues that the depicted tube joint extends beyond the cuff in this lateral view, yet it ignores both the contradictory express disclosure in the specification and common sense.

Claim 1 merely requires that the backplate "define a passage." It makes no mention of the airway tube, or how the backplate passage transitions to the airway tube, nor need it do so. See Ventana, 473 F.3d at 1181; Golight, 355 F.3d at 1331. Construing the backplate to require a tube joint simply raises unanswered questions about how to define a tube joint, and what it requires in addition to the claimed passage, if anything.

Extrinsic Evidence b.

Dr. Lampotang's opinion concerning the construction of the claim term "backplate" is extrinsic evidence which is entitled to no weight because Ambu has identified no ambiguity in the meaning of the term that is not resolved by the intrinsic evidence. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence."); Sunrace Roots Enter. Co. Ltd. v. SRAM Corp., 336 F.3d 1298, 1307 (Fed. Cir. 2003) ("[I]n this case, however, the intrinsic evidence resolves any ambiguity about the appropriate construction of 'shift actuator,' and therefore consideration of extrinsic evidence is inappropriate.").

In any event, Dr. Lampotang's opinions are wholly conclusory and therefore entitled to no weight. *Phillips*, 415 F.3d at 1318 ("conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court"). Dr. Lampotang's opinions (for example, "LMA's proposal renders the term backplate so broad that it would encompass devices clearly lacking a backplate," and that the device described in the '514 patent is an example of a device that "clearly lacks a backplate," Lampotang Open. Decl. ¶ 40) are mere conclusions that are not supported by any reasoning, experimental analysis, or citation to any

references used by those of skill in the art such as professional treatises or references. Dr. Lampotang's "conclusory unsupported assertions... as to the definition of a claim term are not useful to a court." See *Phillips*, 415 F.3d at 1318; *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005) (Noting as not "useful" an expert's declaration that only "quote[d] various passages from the specification" and made "conclusions] about possible embodiments of this invention" without "support[ing] his conclusion with any references to industry publications or other independent sources.").

Indeed, the facts elicited at Dr. Lampotang's deposition reveal significant shortcomings in his declarations. He relied only on documents which were provided to him by Ambu's counsel. Lampotang Dep. 16-17; 25:8-13 (Supp. Stowell Decl., Ex. P). He did not consult with any colleagues, persons of skill, or clinical users, designers, or manufacturers of LMA devices to inform his analysis. *Id.* at 20:16-22. In fact, he spoke with no one other than Ambu lawyers. *Id.* He did no testing of any kind to support his analysis. *Id.* at 24:11-24.

He did no independent searching for documents other than to obtain a list of Dr. Brain's patents by an internet search. *Id.* at 21:7-22:21. But Dr. Lampotang didn't bother to look at the Brain patents located by the search, because there were "too many." *Id.* Had Dr. Lampotang done so, even looking only for use of the disputed claim terms, he would have encountered Dr. Brain's U.S. Patent No. 7,159,589 ("'589 patent") which discloses an "integral airway tube and backplate" that does not have a tube joint. '589 patent col.14 ll.1-3 and Figs. 9E and 9G (Supp. Stowell Decl. Ex. R).

Despite emphasizing having over 50 patents and patent applications, and over 100 publications to his name, Dr. Lampotang did not review any to help form his opinions. Lampotang Dep. 23:18-24:10 (Supp. Stowell Decl. Ex. P). Nor could he identify a single one that related to the design of an LMA device. *Id.* at 39:10-12, 41:23-42:2. The handful of his

⁷ Ambu's arguments in its brief fail for the same reasons; the brief and Dr. Lampotang's declaration parrot each other, word-for-word, and Dr. Lampotang's opinions remain unexplained and unsupported.

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patents identified specifically in his declaration were chosen by Ambu's counsel for reasons unknown to Dr. Lampotang. *Id.* at 162:1-14; (Lampotang Open. Decl. ¶¶ 8-9).

He personally has no experience designing or using an LMA device, other than to insert one in a manikin, in which he could not tell if there was a foldover problem since in a manikin, "we can't see what's going on." Lampotang Dep. 39:16-40:10 (Supp. Stowell Decl. Ex. P). He defines as a person "skilled in the art" someone with extensive educational experience (Lampotang Open, Decl. ¶13), but who need not have any experience designing an LMA device. Lampotang Dep. 163:1-19 (Supp. Stowell Decl. Ex. P).

Whether the declarations contain Dr. Lampotang's independent opinions is doubtful. The declarations were drafted by Ambu's lawyers and Dr. Lampotang only reviewed them and orally suggested edits. Lampotang himself could not recall actually putting pen to paper (or fingers to keyboard) either to draft or edit the declarations. *Id.* at 54-55, 57-58. Comparison of the draft sent to Dr. Lampotang by Ambu's counsel and the final declaration reveal insignificant changes. (Supp. Stowell Decl. Ex. S (comparing draft Lampotang Open. Decl. with the final Lampotang Open. Decl.)); see, e.g., DataQuill Ltd. v. Handspring, Inc., No. 01 C 4635, 2003 WL 737785, *4 (N.D. Ill. Feb. 28, 2003) ("We doubt the value to the trier of fact of a hired expert's opinion when the party hiring him has put words in his mouthor in this case, in his report-leaving him, in essence, a highly qualified puppet."); see also, e.g., Butera v. District of Columbia, 235 F.3d 637, 661 (D.C. Cir. 2001) ("while under Rule 26(a)(2)(B) an attorney may 'assist' in the preparation of an expert's report, the actual preparation of the report goes 'beyond mere assistance.'"); Reliance Ins. Co. v. Keybank U.S.A., No. 1:01 CV 62, 2006 WL 543129, *3 (N.D. Ohio Mar. 3, 2006) ("Although Swiss Re correctly notes that the Federal Rules contemplate that an attorney may provide assistance in the preparation of the report, '... the assistance of counsel contemplated by Rule 26(a)(2)(B) is not synonymous with ghost-writing.""); Stein v. Foamex Int'l, Inc., No. Civ. A. 00-2356, 2001 WL 936566, *5 (E.D. Pa. 2001) (the rules do not permit "blanket adoption of reports prepared by counsel").

Dr. Lampotang has no legal expertise, Lampotang Dep. 94:14-17 (Supp. Stowell Decl. Ex. P), and when he applied legal claim construction standards, he used improper ones. Notably, Dr. Lampotang confessed to committing the "cardinal sin" of claim construction, 8 limiting the claims to the preferred embodiment:

O. . . . Was it your expectation that the claims in the Brain '100 patent should be interpreted to be limited to only the embodiments shown in the specification?

A. Yes.

Id. at 100:17-101:2.

Regarding the term backplate, Dr. Lampotang did nothing to find uses of that term elsewhere in the art, for example in technical or medical dictionaries. Id. at 90-92. Other than the patent in suit, the only other documents using "backplate" that Dr. Lampotang could identify were the Pagan prior art references, id. at 89-90, but in fact they do not contain that precise term, id. at 173:2-9.

With respect to the '514 patent, Dr. Lampotang's analysis is circular and inconclusive. Whether LMA's construction of "backplate" would encompass the structure in the '514 patent is irrelevant. Dr. Brain never argued to the Patent Office that the '100 patent was unique because of a backplate. In particular, he was never required to distinguish the '514 patent in Patent Office proceedings, as it does not address the cuff foldover problem. Likewise, Ambu concedes backplates were known in the prior art generally. (Ambu Br. 5:27; Lampotang Open. Decl. ¶ 26.) But the '514 patent never uses the term backplate, let alone defines the term, nor states whether some or all of the various embodiments of the laryngeal mask device described employ a backplate. The value of the '514 patent for construing the term "backplate" is thus seriously limited. Cf. Arthur A. Collins, Inc. v. Northern Telecom Ltd., 216 F.3d 1042, 1045 (Fed. Cir. 2000) (where the disputed claim term was "TST switch," ///

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See Phillips, 415 F.3d at 1320 (Disapproving of "one of the cardinal sins of patent law-reading a limitation from the written description into the claims," citing SciMed Life Sys., 242 F.3d at 1340).

the Court relied on cited prior art references that referred to "switches with time-switch inputs and outputs...as TST switches.").

LMA's construction of backplate requires that the body be "surrounded by and more rigid than the cuff." Whether Dr. Lampotang is correct that the rubber sheet in one of the embodiments in the '514 patent is more rigid than the cuff when it is supported by the cut-off tube does not impact the propriety of LMA's construction. The '514 patent discloses that the device could be designed with or without a rigid material forming a backplate⁹ and thus LMA's construction would properly cover an embodiment of the '514 patent having a rigid mask. Whether a design with a cut-off tube and rubber sheet "clearly lacks a backplate" as Ambu contends (Ambu Br. 13:14) is a purely academic debate. Ambu does not employ such a design and the '514 patent was not listed as invalidating prior art in Ambu's Preliminary Invalidity Contentions.

With respect to the internal LMA memo that Ambu states demonstrates that the term backplate cannot mean a "body surrounded by and more rigid than the cuff," whatever the memo may mean, it is not part of the public record of the '100 patent. Thus it cannot be used to vary the meaning of the term based on the claim language, specification, and prosecution history. "Extrinsic evidence...cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence." *On-Line Tech. v. Bodenseewerk Perkin-Elmer GMBH et al.*, 386 F.3d 1133, 1139 (Fed. Cir. 2004) (citing Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003) ("When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.") (other citations omitted)). Moreover, an internal company memo is not the type of extrinsic evidence that the Federal Circuit has sanctioned for use in claim construction. See *supra*, at 8-9. This is particularly true here since Ambu presents no testimony from the authors or recipients of the memo, nor evidence regarding the level of

⁹ For example, the '514 patent states that when a reusable device is needed the "mask portion may be made of a relatively rigid sterilisable material." '514 patent, col.3 ll.3-31 (Woo Decl. Ex. E.)

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skill of those individuals. See Lampotang Dep. 199:4-23 (Supp. Stowell Decl., Ex. P). As such, it should be accorded no weight.¹⁰

"The cuff being attached to the backplate" 2.

LMA's Proposed Construction	Ambu's Proposed Construction
	The cuff is a separate structure from the backplate and is made fast, as by gluing or welding it, to the backplate.
"attached"—united, connected, or joined, regardless of the method of construction	"attached" means making fast, as by gluing or welding together, two or more separate items.

Ambu continues to avoid the definition of "attached," the actual term used in the claim. In the Joint Claim Construction Chart, Ambu cited a dictionary definition of the verb "attach" instead of a definition of the adjective "attached." In its opening brief, Ambu also relies upon the dictionary definition of "attachment." 11 Neither definition can trump the definition of the claim term itself.

Ambu argues that the specification's disclosure of molding the device as a single "unitary piece" is an alternative to attachment, not a species of attachment. But the '100 patent not only refers to these two distinct embodiments as alternatives, it also treats them both as part of the same genus. When first described in detail, the cuff and backplate are referred to as "united," without mention of manufacturing details. '100 patent col.4 1.55. Next, in the paragraph beginning at column 6, line 11, both embodiments, the "bonding" process and the "extruded as a single unitary piece" manufacturing process, are described as alternatives. In the very next paragraph, the device is described again generically as the backplate "attached to the main-cuff" in the context of how the distal rib interfaces with the cuff. Id. at col.6 1.26. While the manufacturing process is identified in the specification, the

Even if it were the type of extrinsic evidence that could be considered, its persuasive value is diminished by the fact that Ambu presented Dr. Lampotang with another internal LMA document that describes the same Ambu device as having a "backplate." (See Supp. Stowell Decl., Ex. T (LMA 6735); cited in Lampotang Open. Decl., Ex. B.)

Ambu failed to cite this definition in its disclosure of extrinsic evidence in the Joint Claim Construction Chart.

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function of the resulting united cuff and backplate structure does not vary as a result of the manufacturing technique. Consistently, nothing in the claims is directed to the manufacturing process, nor does the specification suggest that only one manufacturing process can be used to achieve the goals of the invention.

Ambu strains to force the word "attached" to imply a method of attachment. But even if unitary molding were not a method of attachment, the resultant backplate and cuff are nonetheless attached, just as our arms are attached to our bodies despite never having been separate. The logical conclusion is that the manufacturing details of how the cuff and backplate come to be united are neither critical to the invention, nor claimed in the '100 patent. 12

Ambu argues that the '743 patent, which is incorporated by reference in the '100 patent, "explains that one piece molding precludes the existence of a backplate." (Ambu Br. 19.) In alleged support for that proposition, Ambu argues that "one of the stated objects of the '743 patent is to 'eliminat[e] the need for a separate back plate part." Ambu fails to recite the rest of that sentence which goes on to say, "in that the moulded back plate is an integral part of the peripheral annular formation." Instead of saying that one piece molding precludes the existence of a backplate, it makes direct reference to a backplate in the part of the sentence that Ambu omits.

Finally, Ambu's construction is inconsistent with another item of intrinsic evidence, Dr. Brain's U.S. Patent No. 5,355,879 ("879 patent"), which is also expressly incorporated by reference into the '100 patent col.5 1.40, and cited on the face of the '100 patent. See Kumar v. Ovonic Battery Co., Inc. 351 F.3d 1364, 1368 (Fed. Cir. 2003) ("prior art cited in a

Consistent with LMA's conclusion, Dr. Lampotang defined the background of one skilled in the relevant art (Lampotang Open. Decl. ¶ 13) and acknowledged that experience with manufacturing techniques is not a requirement to satisfy his standard. Lampotang Dep. 164-67 (Supp. Stowell Decl. Ex. P).

Ambu mischaracterizes this excerpt. The stated object is not to eliminate the backplate; rather, eliminating the backplate is the means for realizing the "second-stated object" which is integrally connected molding of the inflatable ring and backplate components in a single operation. '743 patent col.3 ll.30-34, col.2, l. 67 - col.3 l.2 (Woo Decl. Ex. L).

patent...constitutes intrinsic evidence"). The '879 patent discloses one laryngeal mask embodiment wherein the backplate and cuff are "separately molded" and "adhesively assembled," '879 patent col.3 l.5-18, and another embodiment wherein "the entire mask" (*i.e.*, the backplate and cuff) "is the product of a single molding operation," *see id.* col.4 ll.8-11 (Supp. Stowell Decl. Ex. U).

The intrinsic record of the '100 patent thus makes repeated disclosures of embodiments wherein the cuff and backplate are *either* separately molded and physically joined together in a manufacturing step *or* molded in a single-piece construction. The claims do not indicate that they were directed to only one of those embodiments.

- 3. At least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff
 - a. "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff"

LMA's Proposed Construction	Ambu's Proposed Construction
The phrase requires no construction and should have its plain and ordinary meaning.	The phrase means: "A portion of the posterior wall of the cuff where it attaches to the distal end of the backplate is thickened and stiffened by a reinforcement extending from the distal end of the backplate."

Without identifying any term or phrase in this lengthy claim element that needs construction (a prerequisite to claim construction), Ambu argues extensively why the claims should be limited to embodiments having a backplate extension to reinforce the cuff. This is simply improper. Claim construction is not a process for re-writing the claims in order to direct them to what a party perceives to be the "gist" of the invention; it is a process by which words and phrases already present in the claims are construed. Ambu fails to identify any specific claim term in this lengthy phrase that does not have its ordinary meaning. Ambu's attempt to shoehorn a backplate extension limitation into this claim language is therefore *prima facie* improper. *Renishaw v. Marposs Societa Per Azoni*, 158 F.3d 1243, 1252 (Fed. Cir. 1998) (requiring that claim language must first be found to be in need of construction).

Even if it was proper to import limitations based on the "gist" of the invention – which it is not – Ambu is wrong that the specification describes the "invention" in terms of a backplate extension and that a backplate extension is the only means described for reinforcing the cuff. (Ambu Br. 20-21.) First, as set forth in LMA's opening brief and supra at 6-8, the first two paragraphs of the Summary of the Invention describe the "present invention" in terms of cuff reinforcement without any mention of backplate extension. Then, in a "preferred aspect" immediately thereafter, the specification teaches that the cuff can be reinforced by extending the backplate. Ambu can point to no language in either the specification or the prosecution history where the patentee described the present invention (as opposed to a preferred embodiment or detailed description thereof) as requiring a backplate extension. Indeed, in the Summary of the Interview on May 22, 2006 (see Lampotang Open. Decl. ¶ 58, Ex. N), the patentee distinguished the claims as patentable without any reference or reliance upon a backplate extension ("[applicant's representatives] pointed out that the amended claim language with the limitations of 'at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff' is readable over the Pagan reference in that the Pagan reference does not disclose a rib."). That is because the patentee had already cancelled claims directed to the "backplate having a distal rib" and substituted different claims - that ultimately issued - which call instead for a thickened cuff. (Compare Lampotang Open. Decl. Exs. R & M.)

Ambu's reliance upon Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340 (Fed. Cir. 2004), Alloc, Inc. v. ITC, 342 F.3d 1361 (Fed. Cir. 2003), and Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312 (Fed. Cir. 2006) is misplaced, because the asserted patent(s) in each of those cases characterized the "present invention" as embodying the disputed limitation. The '100 patent does not and those cases are thus inapposite.

In *Microsoft*, the Court limited the claimed communications to those over a telephone line and excluded communications over a packet-switched network such as the Internet, because the specification and prosecution history referred to both the "present invention" and every embodiment in terms of communications "over a standard telephone line." Microsoft

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27 28 Corp., 357 F.3d at 1348.

The "Summary of the Invention" portion of the specification states that the claimed personal communications system includes "hardware to enable voice, fax and data communications with a remote site connected through a standard telephone line," as well as circuitry to "transfer [data] over the telephone lines to a remote site."

Those statements, some of which are found in the "Summary of the Invention" portion of the specification, are not limited to describing a preferred embodiment, but more broadly describe the overall inventions of all three patents... In fact, the specification refers to data transmission "over" or "through" a telephone line roughly two dozen times. Nowhere does it even suggest the use of a packet-switched network. In light of those clear statements in the specification that the invention ("the present system") is directed to communications "over a standard telephone line," we cannot read the claims of the '627 patent, the '649 patent, or the '532 patent to encompass data transmission over a packetswitched network such as the Internet. (Citations omitted). []

Furthermore, ... [] Multi-Tech [] provide[d the following] "summary of the invention" [during prosecution]:

In their specification, Applicants disclose a communications system which operates over a standard telephone line...commonly referred to in the art as a "plain old telephone service" (POTS) line..... Applicants' invention . . . transmits the packets across a POTS line to a remote site . . .

....That statement unambiguously reflects Multi-Tech's own understanding of its inventions in the '627, '649, and '532 patents as being limited to the transmission of data packets over a telephone line.

Id. at 1348-49 (emphasis added).

In Alloc, claims directed at a flooring system were construed to require "play" (i.e., a space) between a locking groove on a first panel and the locking element of a panel adjacent to the first panel because "the claims recite floor system features...in which play is necessarily present" and the "specification describes 'the invention' under the heading, 'Technical Problems and Objects of the Invention,' as provid[ing] a system...where play exists between the locking groove and a locking surface...." Alloc, 342 F.3d at 1368; see also id. at 1369 ("[i]n addition to a first mechanical connection, the specification states that 'the invention' provides for a second mechanical connection wherein 'a play exists' between the locking groove and a locking surface on the locking element...").

Similarly, in *Honeywell*, the claimed "fuel injection system component" was construed as limited to a fuel filter because "on at least four occasions, the written description refers to the fuel filter as 'this invention' or 'the present invention.'" Honeywell, 452 F.3d at 1318 (citations to the patent specification omitted).

Second, Ambu is wrong that an extended backplate is the only means described for reinforcing the cuff. As discussed above, the specification describes a "second embodiment" both in the context of applying the "distal rib of the backplate to the posterior surface of the" cuff (embodiment "2(a)"), and in the context of "thickening" the cuff wall (embodiment "2(b)"). Specifically, the '100 patent discloses that "[t]he distal rib 105a may be effectively constituted by a thickening of the posterior wall of the distal region 60a of the inflatable main cuff 55a, and as shown, forms a distal extension of the bowl of the backplate 52a." '100 patent col.8 ll.9-12 (emphasis added). This disclosure confirms that, instead of the reinforcement being an extended backplate, the reinforcement instead "may be" a thickened cuff wall which functions "effectively" like the extended backplate embodiment.

This passage continues and points out that what is "shown" in the figures "forms a distal extension" of the backplate. Notably, this is the only place in the '100 patent which refers to an "extension" of the backplate, as opposed to the backplate being "extended." See, e.g., id. at col.1 1.66. Indeed, an "extension" is not necessarily contiguous with the original structure (whereas when a structure is "extended," continuity is implicit). For example, a university "extension" implies a separation from the main campus.

Even if this passage were referencing the earlier extended backplate embodiment, the context suggests that reference is only made in a comparative sense. The passage expressly describes a literal thickening of a particular section of the cuff wall, which is not part of the backplate. Overall, this passage conveys that there may be a thickened cuff wall embodiment ("2(b)"), with no mention of it literally being joined to the backplate; the joined embodiment is like the one shown in the drawing, but other embodiments that are not joined are simply not shown in the drawings.

Reading the second embodiment as having two distinct subparts is consistent with the "present invention" language of the Summary of the Invention, which generically discloses that a reinforcement is "incorporated into the cuff." '100 patent col.1 1.52. Later in the Summary of the Invention, the patentee describes use of an extended backplate as "a preferred aspect." While that was the embodiment chosen to be illustrated, the claims can

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nonetheless encompass a described, but not illustrated, embodiment. Nazomi Commc'ns., Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005) (claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification").

Even if a cuff reinforcement by means other than extending the backplate were not explicitly disclosed in the specification, a claim directed at such a minor variation to the disclosed embodiments would be permissible:

[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention. A specification may, within the meaning of 35 U.S.C. § 112 para. 1, contain a written description of a broadly claimed invention without describing all species that the claim encompasses.

Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003) (internal citations omitted). The case law cited by Ambu likewise acknowledges the claims may "cover more than the specific embodiment shown." Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998).

The Federal Circuit has only limited claims to the embodiments expressly disclosed in the specification "when the *entirety* of the specification *clearly* indicates that the invention is of a much narrower scope." Cordis, 339 F.3d at 1365 (clarifying the holding of Gentry Gallery). This exception applies only when a given element is "conveyed as critical to the invention" or is "described as the only feasible design in the disclosure." Id. In this case, not only does the specification expressly disclose a "thickening of the posterior wall of the . . . inflatable main cuff," but nothing in the specification describes any particular embodiment as "critical" or "the only feasible design."

At best Ambu can argue that a greater portion of the specification was focused on reinforcement of the cuff by extending the backplate as a solution to preventing cuff foldover. However, it is well settled that limitations should not be read into otherwise unrestricted claims based on the primary focus of the patent's solution to the problem. Sunrace, 336 F.3d at 1305 (reversing lower court's construction of the term "shift actuator" to require a cam because "while it is clear that the patentee was primarily focused on an embodiment of his invention using a cam, nothing in the patent limits the claims to that embodiment").

Ambu also offers the rationale that the reinforcement must be continuous with the backplate to prevent the gap between the backplate and the thickened cuff from forming a weakness or crease at which point the cuff folds. (Ambu Br. 20.) No mention of this concern is present in the '100 specification. Moreover, Dr. Lampotang conceded that the cuff could fold at other locations throughout the cuff, not just at a discontinuity between the backplate and the thickened cuff. Lampotang Dep. 116:16-25 (Supp. Stowell Decl. Ex. P). In fact, the accused Ambu device includes a discontinuity between the backplate and the reinforced cuff, and Ambu has advertised the design as preventing foldover. (Supp. Stowell Decl. Ex. V (Ambu AuraOnce Brochure).) Regardless, even if a rib which forms a continuous backplate extension were better able to prevent foldover, that is immaterial since "[i]nefficient infringement is infringement still." *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 792 (Fed. Cir. 1990) (citing *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 859 (Fed. Cir. 1988) ("That application of the doctrine arises out of a recognition of a second real-world phenomenon: inefficient infringement is still infringement.")).

b. <u>"at least a portion"</u>

LMA's Proposed Construction	Ambu's Proposed Construction
some or all	The term "at least a portion" does not require separate construction. It has its plain meaning.

Ambu admits there is no real dispute and that the phrase at issue "means some and could include all," consistent with LMA's construction. (Ambu Br. 23.)

c. "Thicker and stiffer than other portions of the cuff"

LMA's Proposed Construction	Ambu's Proposed Construction
	The term "thicker and stiffer than other portions of the cuff" means thicker and stiffer than <i>any</i> other portions of the cuff <i>walls</i> (emphasis added).

Ambu inserts the words "any" and "walls" into the claim language as its proposed construction. Again, Ambu does not identify any word in the claim as needing construction

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and thus requiring the importation of these additional terms. Instead, Ambu argues that the description in the specification that reads, "[t]he main-cuff 50 has a thin-walled construction and the reinforcing distal rib 105 has an intermediate thickness and compliancy" "makes clear" that "all" portions of the wall other than the reinforced portion have a thin-walled construction. However, "all" is nowhere in the specification and there is no basis for importing such a limitation. Dr. Lampotang appears to adopt a similar view to LMA. The construction he proposes reads in pertinent part, "less flexibility than other parts of the cuff" and does not import the word "any" to modify "other parts." (Lampotang Open. Decl. Ex. D.)

Ambu's construction should be rejected because it is a transparent attempt to allow insignificant variations in the design of the cuff to avoid infringement. If "any" thickening of the cuff in a location other than the distal region would avoid this claim limitation, Ambu could potentially add a minute bump in the proximal region of its cuff, and argue that alone avoids infringement. In fact, the accused Ambu product has a thickened cuff which extends past the arbitrary line that Ambu contends delineates the "distal region." (See Stowell Decl. Ex. O (physical sample).). If Ambu's definitions of both "distal region" and "thicker and stiffer" are adopted, it no doubt will assert that it avoids infringement simply by thickening more of its cuff than is shown in the preferred embodiment of the '100 patent. Nothing in the intrinsic record supports such a restrictive reading of the claim scope.

В. **Dependent Claims**

1. Claim 2 - "more compliant than the backplate"

LMA's Proposed Construction	Ambu's Proposed Construction
Requires no construction and should receive its plain and ordinary meaning	Indefinite. Alternatively, it means: less rigid and stiff than the backplate

Ambu states that "the parties do not appear to dispute the meaning of this limitation," but observes that "compliant is not usually used to describe the stiffness of an object." (Ambu Br. 23.) However, Ambu's expert does not adopt Ambu's "less rigid and stiff" construction and instead proposes "more elastic than all of the backplate." (Lampotang

Open. Decl. Ex. D.) LMA maintains its position that there is no reason to substitute "less rigid and stiff" or "more elastic" for "more compliant" and the plain meaning of the term is sufficiently clear that no construction is required.

2. Claim 3 - "distal rib"

LMA's Proposed Construction	Ambu's Proposed Construction
A stiffener or reinforcement which is smaller than the portion of the cuff which it stiffens or reinforces	An extension of the backplate that is rib- shaped, narrower than the diameter of the tube adapted to fit the tube joint, and more rigid than the backplate, that reinforces and stiffens the region of the cuff extending distal to the backplate.

As discussed in LMA's opening brief (LMA Br. 19-21), the proper construction of "rib" is consistent with its common usage given that it is not a term of art and it should not be limited to preferred embodiments.

Ambu's proposed definition again seeks to read in numerous limitations from the preferred embodiment. The claim says nothing about the relationship between the thickened cuff portion and the backplate and, as discussed above at page 22, there is express disclosure of an embodiment in which the reinforcement is not part of the backplate. Nor do the claims refer to the airway tube, let alone the size of the rib relative to the tube. Nor should they, as the rib reinforces the cuff, not the tube. One would expect the rib to be smaller than the portion of the cuff which it reinforces, as in LMA's definition, but it makes no sense to imply into the claim a rib size relative to the tube, when the tube is completely disassociated from the rib.

Ambu cites the same portion of the prosecution history that LMA cites as alleged support for its attempt to import an additional limitation that the rib be narrower than the diameter of the tube. Ambu points out that in 2001 claims with such a limitation were found to be allowable. What Ambu does not point out is that in 2005, when similar claims were reintroduced, LMA expressly pointed out to the examiner that they had been previously allowed, but that "the only difference between new independent claim 34 and old claim 1 is that the clause which reads, 'wherein the distal rib is narrower than the diameter of a tube

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adapted to fit into the tube joint' has been deleted from new claim 34." (Stowell Dec. ¶ 9, Ex. H at 4 (emphasis added).) Thus, the prosecution history does not support in any way that the issued claims should have the implicit limitations that were explicitly cancelled. In fact, it supports just the opposite—that the patentee did not intend to so limit the claims and that the Patent Office, after having seen such a limitation, allowed the claims to issue without it.

Lastly, Ambu seeks to include in the definition a shape requirement – "rib-shaped" – yet its own witness apparently is unsure what that shape is. (Compare Lampotang Open. Decl. ¶ 66 (rib is "a stiff member that curves"); Lampotang Resp. Decl. ¶ 29 (rib is "straight")). The term rib has a well understood functional meaning as a reinforcing member. The specification does not warn against, or otherwise expressly disclaim, any particular shape or design for the resulting rib. Ambu's proposed construction unnecessarily complicates this simple term.

3. Claim 4 - "longitudinal distal rib"

LMA's Proposed Construction	Ambu's Proposed Construction
A distal rib running lengthwise	An elongate, distal rib running lengthwise, i.e. in the direction of the proximal end of the mask

Although Ambu seeks to limit the shape of the claimed "longitudinal distal rib" to an "elongate" shape, its opening brief fails to provide any explanation for why a "longitudinal" distal rib is necessarily elongate or explain precisely what it means by "elongate," a term which itself would also require a construction. (See LMA Br. 22.)

Ambu's proposed construction is also flawed because its proposed construction refers to a direction ("in the direction of the proximal end of the mask") without specifying a frame of reference, i.e., from where one starts when proceeding "in the direction of the proximal end of the mask." Indeed, Ambu appears to attempt to cover up its failure to specify that starting point in its proposed construction when it argues in its brief that "lengthwise is the direction running from the tube-joint toward the distal end of the cuff' (notwithstanding that its proposed construction says it runs toward the proximal end). (Ambu Br. 27.)

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Claim 6 - "proximal portion of the passage," "passage axis" 4.

	LMA's Proposed Construction	Ambu's Proposed Construction
"proximal portion of the passage"	The portion of the passage nearest to the person inserting the device	The tube-joint proximal to the bowl of the backplate ¹⁴ The portion of the backplate passage nearest to the outer extreme of the laryngeal mask device, i.e. the tube-joint on the backplate for connecting to the airway tube ¹⁵
"passage axis"	An imaginary straight line extending along the centerline of the proximal portion of the passage	The tube-joint axis

As an initial matter, Ambu has changed its proposed construction for the phrase "proximal portion of the passage" from the one included in the Joint Claim Construction Chart filed with the Court. Ambu has done so without seeking leave of the Court and without providing notice of this change to LMA before or after filing and serving its Opening Claim Construction Brief. Ambu's untimely change of its proposed construction has deprived LMA of the opportunity to address Ambu's new construction in its opening brief.

However, neither construction is proper because both impermissibly require a tube joint structure, as explained in LMA's opening brief and *supra* at 10-11. constructions are correct because they do not require a tube joint and reflect the ordinary meaning of the claim language.

The parties agree that in the claim language "the backplate defining a passage" from claim 1, the term "passage" means "a path or channel through which air or other gases may pass." However, Ambu argues that under LMA's construction, "the proximal portion of the

¹⁴ Ambu's proposed construction in the parties' Joint Claim Construction Chart filed with the Court on October 6, 2008 [Doc. 89].

Ambu's proposed construction in its Opening Claim Construction Brief filed with the Court on November 25, 2008 [Doc. 114].

backplate passage is a moving target, as a backplate without a tube joint could include an airway tube having varying angles and thus the passage axis may adopt different orientations in the proximal portion of the backplate." (Ambu Br. 28.) Ambu's argument is again based on an impermissible validity argument (*see MBO Labs.*, 474 F.3d at 1332) (Ambu arguing here that absent a tube joint, "this limitation is indefinite") and also fails to recognize that claims may use terms that do not impose absolute boundaries. *See infra* at 30 with respect to discussion of the claim term "distal region."

Lastly, Ambu's latest construction for "proximal portion of the passage" defines the phrase as "the portion of the backplate passage nearest to the outer extreme of the laryngeal mask device." Nowhere does Ambu explain what structure represents the "outer extreme of the laryngeal mask device" and this language is certainly not clearer than LMA's plain language interpretation.

C. Claim Terms Defined To Assist the Finder of Fact

Claim Term	LMA's Proposed Construction	Ambu's Proposed Construction
Distal Region (claim 1)	The region of the cuff at the end most distant from the person inserting the device	The region of the cuff distal to the backplate, i.e. the leading edge of the cuff
"laryngeal inlet" (claim 1)	The opening to the larynx which is located at the base of the throat its plain meaning	
"posterior" (claim 1)	The back side of the device, i.e. the side that is nearer to the patient's back when the device is in its inserted position Located nearer to the back of the patient's body	
"anterior surface" (claim 5)	The front surface of the cuff, i.e. the surface that is nearer to the patient's front when the device is in its inserted position	The surface located nearer to the front of the patient's body.
"proximal portion" (claim 6)	The portion at the near end to the person inserting the device	Does not need separate construction; has its plain meaning.
"acute" (claim 6)	Between zero and ninety degrees	Does not need separate construction; has its plain meaning.

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"Distal region," "proximal" and "distal" are terms of reference that the specification defines in terms relative one to the other:

The anatomical terms "proximal" and "distal" with respect to applying an instrument to the human body, refer to locations nearer to the operator and to the inside of the body, respectively. Alternatively, "distal", as opposed to "proximal", means further away from a given point; in this case, "distal" is used to refer to positions on the LMA-device 20 or in the body relative to the extreme outer or connector end of the LMA-device. "Proximal" is the opposite of "distal".

'100 patent col.4, ll.1-9.

The specification does not set any absolute boundary for these relative terms, nor would any be appropriate. "Distal" is a contextual term and thus the precise size and shape of the cuff needs to be considered in assessing the boundaries of its distal region. Analogously, one would need to know the geography of a country before identifying a boundary of its "northern" region. The specification gives several criteria relating to this analysis, such as in describing the proximal region 57 as "wider" and the distal region 60 as "narrower." Where this transition from wider to narrower shape occurs can vary. Likewise, the specification describes the distal region as "shaped to conform with the base of the hypo-pharnx," and entering the upper esophagus. *Id.* at col.4 1.64 - col.5 1.1. Lastly, the distal region, or "distal end" of the device, is where the risk of cuff foldover may occur. Id. at col.1 ll.30-35. A bright-line test of the kind advocated by Ambu ignores how the LMA device conforms to the patient's anatomy.

Terms that denote location are well-accepted in claim language even when not sharply bounded. The Federal Circuit has found error by a district court that held claim terms including "approach each other," "close to," and "closely approximate" to be indefinite, stating: "[t]he criticized words are ubiquitous in patent claims. Such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts." Andrew Corp. v. Gabriel Elecs., Inc., 847 F.2d 819, 821 (Fed. Cir. 1988). Similarly, in Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F. 3d 1298, 1310-11 (Fed. Cir. 2003), the Federal Circuit considered the term "generally parallel" and endorsed the common use of approximate terms in patent claims "to avoid a strict numerical boundary to the specified parameter."

In contrast, Ambu has unilaterally set an arbitrary boundary for "distal region" for which it has not cited, and cannot cite, any basis. Ambu states that "Figures 2, 4-5, 7-8 and 10 all further confirm that the "distal region 60" is the leading edge of the cuff." (Ambu Br. 16.) Ambu skips over Figure 3 which has a lead line for distal region 60 that points to an area proximal to the distal tip of the backplate. If one draws a longitudinal axis on Figure 3 and then draws a line perpendicular to that axis and intersecting it at the distal tip of the backplate, lead line 60 points to a spot *proximal* to the distal tip of the backplate. Ambu does not even attempt to reconcile Figure 3 with its definition because it cannot. Indeed, the line that Dr. Lampotang drew at his deposition to delineate the distal region of Figure 3 suffers from exactly this problem in that lead line 60 is outside the distal region as Ambu defines it. Lampotang Dep. 206:5-207:16, Ex. 1, Fig. 3 (below) (Supp. Stowell Decl. Exs. P & Q).

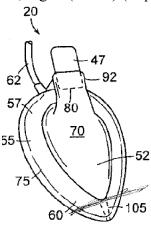


FIG. 3

Ambu also misstates the patent when it cites to the specification. Ambu quotes column 8, lines 39-41: "distal region of the fully deflated main-cuff is the leading end of the LMA-device." However, Ambu then re-characterizes "leading end" as "leading edge" in order to support its proposed claim construction. Instead, "leading end" supports LMA's proposed construction that the distal region is the region "at the end most distant from the person inserting the device."

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Importantly, the accused Ambu product includes a thickened cuff wall in a distal location which, even under Ambu's construction, would qualify as the "distal region." Thus, the precise delineation of this boundary will not be necessary for the infringement analysis. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331 (Fed. Cir. 2006) (permitting courts to consider the accused product to "supply the parameters and scope of the infringement analysis, including its claim construction component").

Regarding "anterior surface", unlike Ambu's construction, LMA's construction provides the necessary context of the device being "in its inserted position," and is therefore more helpful to the trier of fact. Similarly, as stated in LMA's opening brief, providing definitions for the terms "laryngeal inlet" and "acute" will assist the fact finder.

IV. <u>CONCLUSION</u>

For the foregoing reasons and those in its opening brief, LMA respectfully requests that the Court adopt LMA's proposed claim constructions in addition to the parties' agreed-upon claim constructions, as set forth in the Joint Claim Construction Chart.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2009, I caused the foregoing PLAINTIFFS' RESPONSIVE CLAIM CONSTRUCTION BRIEF to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the applicable registered filing users.

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I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Dated: January 14, 2009

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